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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,330	08/08/2006	Minas Theodore Coroneo	37528-503N01US	6478

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
03/17/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,330	CORONEO, MINAS THEODORE	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the reply filed 1/3/11, applicant amended claims 19-21 and added new claims 32 and 33. Claims 19-21 and 31-33 are currently pending.

Response to Arguments

Applicant's arguments filed 1/3/11 have been fully considered but they are not persuasive.

First, regarding the 112 first paragraph rejection of Claims 19 and 21, applicant argues that Figure 3 depicts the claimed configuration. However, the figures are illegible as they appear to be scanned images that are largely blacked out (see drawing objection below). The claimed conical shape can not be readily identified in Figure 3. Applicant is requested to resubmit these figures.

Second, applicant argues that Solomon does not teach that the proximal portion of the implant is flush with the outer surface of the cornea. However, it is the examiner's position that at least a portion of Solomon's proximal portion is flush with the cornea.

Applicant more clearly states in newly filed claims 32-33 that the proximal end has a flat outer surface that lies flush with the outer surface of the cornea. Although this language overcomes the Solomon patent, a new grounds of rejection has been made in view of newly considered prior art (Richter – see rejection below).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not specifically state that the distal end of the implant is cone-shaped such that the diameter of the distal end gradually reduces moving in the distal direction.

It is important to note that, although applicant claims that Figure 3 depicts the claimed configuration, the figures are illegible as they appear to be scanned images that are largely blacked out (see drawing objection below). The claimed conical shape can not be readily identified in Figure 3.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings currently filed appear to be scanned images in which substantial portions are blacked out. Specifically, the specific structural characteristics

of the implants can not be distinguished in Figures 1-3. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19, 21, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon (US 5,626,559).

3. With respect to Claim 19 and 21, Solomon teaches an ocular pressure spike shunt comprising a fluid transfer tube made from a biocompatible, substantially flexible material such as silicone or Teflon (Column 2, Lines 23-28). The tube has an inner (distal) end 26, an outer (proximal) end 12', a tubular lumen 14 disposed therebetween, and a one-way valve 36 for maintaining pressure in the eye at a normal level, said valve opens to permit fluid flow through the tube when a predetermined pressure is exceeded (Column 2, Lines 61-65). When implanted in the eye, the shunt is disposed such that at least a portion thereof is substantially flush with the outer surface of the cornea, and the distal end opens into the anterior chamber of the eye on the inner surface of the cornea. The implant is fully capable of being inserted into an ocular paracentesis incision port

and removed from the eye after treatment is complete. See Figures 1-5. Regarding claim 21, Solomon teaches a method of implanting an ocular shunt as described above, comprising forming an incision in the eye, and introducing the shunt through the incision such that the outer end is flush with the surface of the cornea and the inner surface extends into the anterior chamber of the eye (see Abstract). Solomon further teaches an anchoring means at both ends of the tube (proximal anchor 12 at the proximal end and distal anchor 28 at the distal end), said anchoring means comprising enlarged diameters. The proximal anchor 12 comprises edges that are substantially flush with the outer surface of the cornea upon implantation, and the distal anchor comprises an enlarged diameter 28 that is positioned flat against the inner surface of the cornea. Further, Solomon teaches that the distal end of the shunt (i.e. the distal anchor) is cone-shaped, such that the diameter of the distal tip is smaller than the rest of the anchor (see Figure 1).

4. With specific respect to Claim 31, Solomon teaches one embodiment (Figure 3) wherein the tubular portion has a length that is substantially equal to the thickness of the cornea. Solomon clearly teaches that the implant is designed such that the implant is sized such that the proximal and distal anchors abut the outer and inner walls of the cornea, respectively. The tubular portion therefore has a length that corresponds to the cornea's thickness (see entire disclosure).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon in view of Brown et al. (US 5,743,868). Solomon teaches the ocular shunt substantially as claimed, and further teaches that the unidirectional valve is configured to open when fluid in the anterior chamber exceeds a predetermined pressure (Column 2, Lines 61-65). Solomon, however, does not specifically teach that the unidirectional valve operates such that a 10 mmHg pressure differential is maintained. Brown discloses an ocular implant for regulating pressure between the anterior chamber and the exterior of the cornea such that the pressure difference is kept at 10 mmHg, which is considered to be a normal pressure in the anterior chamber (Column 6, Lines 37-44). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the unidirectional pressure control valve of Solomon to regulate fluid flow such that a 10 mmHg pressure differential is maintained in order to keep the anterior chamber of the eye at a natural pressure level.

6. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon in view of Richter et al. (US 6,468,283). Solomon teaches the ocular

shunt substantially as claimed, but does not specifically teach that the *outer surface of the proximal end* lies flush with the outer surface of the cornea when implanted. Richter et al. (hereafter 'Richter') teaches an ocular implant for regulation of anterior chamber pressure wherein the implant comprises a shunt that extends from the anterior chamber to a bleb on the outer surface of the eye. Specifically, the shunt comprises a proximal end having a rounded disc that abuts against the outer surface of the eye (in this case, the sclera). The disc comprises a substantially flat structure with a fluid opening in the top portion thereof, such that the outer wall of the proximal end of the shunt lies substantially flush against the anatomy of the eye. This arrangement allows a fluid bleb to be created on top of the disc as fluid drains from the anterior chamber (Figures 5-7). Importantly, Richter teaches that this specific configuration serves the purpose of raising the conjunctiva such that a bleb may be formed and clogging of the passageway is prevented (see Column 6, Lines 30-51). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Solomon's intraocular drainage shunt with a proximal disc that lies flush against the surface of the eye, as suggested by Richter, in order to provide a well known, alternate, more compact means for creating a fluid bleb on the outer surface of the anterior chamber in an intraocular drainage shunt.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
12 March 2011